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No. ——

In The Supreme Court of the United States

UNIVERSAL MANAGEMENT SERVICES, INC., NATURAL CHOICE, INC., PAUL M. MONEA, AND PAUL A. MONEA,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. May a District Court properly order restitution as a sanction in a civil action under the Food, Drug and Cosmetic Act ("FDCA") when both the Act and its legislative history appear to preclude this remedy?

2. May a company employee who did not own, manage, or control the corporate defendants and who had no role in or knowledge of the companies' decision not to seek pre-market approval be held liable as a matter of summary judgment under the FDCA for the unauthorized distribution and sale of products?

PARTIES TO THE PROCEEDING

PETITIONERS

Universal Management Services, Inc., Natural Choice, Inc., Paul M. Monea, and Paul A. Monea.

RESPONDENT

The United States of America.

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PETITION FOR WRIT OF CERTIORARI

OPINIONS BELOW

Petitioners seek review of the September 13, 1999, opinion of the United States Court of Appeals for the Sixth Circuit, reported at 191 F. 3d 750 (6th Cir. 1999). See Appendix A. This opinion affirmed the opinion of Judge Solomon Oliver, Jr., United States District Court for the Northern District of Ohio — his December 22, 1997 order granting summary judgment in favor of plaintiff United States of America, reported at 999 F.Supp. 974 (N.D. Ohio 1997). See Appendix B.

This petition has been filed within 90 days of December 2, 1999, the date the Sixth Circuit filed its denial of the Petition

for Rehearing based on the Sixth Circuit's Opinion issued on September 13, 1999. See Supreme Court Rule 13.

JURISDICTION

This petition has been filed within 90 days of December 2, 1999 the date the Sixth Circuit filed its denial of the Petition for Rehearing based on the Sixth Circuit Opinion issued on September 13,1999. *See* Supreme Court Rule 13. The Court's jurisdiction is invoked pursuant to 28 U.S.C. §§ 1254(1) and 2106

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the following constitutional and statutory provisions, the pertinent portions of which are set forth below:

> No State shall make . . . . abridge the privileges or immunities . . . . deprive any person of life, liberty, or property, without due process of law . . .

U.S. Const., Amend. XIV.

> The following acts . . . . are prohibited . . . . interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded . . . .failure to register . ...

21 U.S.C. § 331 (a) (k) and (p)

> The district courts . . . . shall have jurisdiction . . . . to restrain violations of (Federal Food, Drug, and Cosmetic Act).

21 U.S.C. § 332 (a)

> any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty .

21 U.S.C. § 333 (f)

PROCEDURAL HISTORY & STATEMENT OF THE CASE

The Food and Drug Administration ("FDA") initiated this action against Petitioners Universal Management Services, Inc. ("UMS"), Natural Choice, Inc. ("Natural Choice"), Paul M. Monea ("Monea Sr."), and Paul A. Monea (Monea Jr.") on December 21, 1995 . The FDA alleged that UMS's sales of the "Stimulator," a hand-held instrument which emits a small electric charge and is intended to relieve certain types of physical pain when applied to accupressure points, violated the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* The FDA sought both injunctive relief and a disgorgement of profits. UMS and Natural Choice are Ohio corporations with their principal places of business located in Akron, Ohio. Monea Sr. is the principal of UMS and Natural Choice. His son, Monea Jr., was an employee of UMS who answered to his father and who was in charge of shipping and other day-to-day activities.

Contemporaneously with the filing of the complaint, the FDA moved for a preliminary injunction to ban Stimulator sales, arguing that because the Stimulator had not been approved for pre-market distribution, it constituted an adulterated medical device being sold in violation of the FDCA. This motion was granted on January 22, 1997. On December 22, 1997, the district court granted the Government's Motion for Summary Judgment, finding that the Stimulator was a medical device, that it was "adulterated," and that it was sold in interstate commerce. The district court rejected the FDA's request for disgorgement but instead ordered restitution to UMS's customers and ordered Petitioners to turn all of their business and financial records relating to Stimulator sales over to the Government.

On January 8, 1998, Petitioners moved for reconsideration on grounds that there was no basis for the district court's resti-

tution order; that Petitioners' former counsel, Edwin Davila, had provided ineffective assistance; that the Stimulator was not a "device" subject to the FDCA; and that there was an absence of evidence as to Monea Jr.'s individual liability. The motion was denied in February 1998. The resulting judgment placed a permanent injunction against the sale of Stimulators and ordered Petitioners to offer full refunds to all customers who bought Stimulators after the May 1995 seizure. Petitioners appealed on March 23, 1998. The lower court's decision was affirmed by a panel of the Sixth Circuit Court on September 13, 1999. On October 28, 1999, Petitioners filed a Petition for Rehearing and Suggestion for Rehearing En Banc which the United States Court of Appeals denied on December 2, 1999. This Petition for Writ of Certiorari is filed within 90 days of the denial of the Petition for Rehearing.

ARGUMENT FOR GRANTING WRIT

There is a split in the Circuit Courts of Appeal and in the Federal district courts over what remedies are appropriate in FDCA actions. The district court's summary judgment order here imposing restitution as a remedy was legally unfounded.

The district court also erred in imposing individual liability upon a defendant who did not own, manage or control any of the corporate defendants. In so doing, the lower court misapplied this Court' s pronouncements that a finding of corporate guilt under the FDCA would extend only to those individuals who have a responsible role in the acts violative of the statute. The district court's decision improperly dilutes the high standard this Court has delineated for individual FDCA liability and sets a dangerous precedent for finding corporate employees accountable for company actions over which they have no control.

ARGUMENT 1

Restitution Is Not an Available Remedy Under the FDCA and the Courts Below Are In Disagreement Regarding Whether Remedies Other Than Injunctive Relief, Seizure, or Criminal Prosecution Are Available

We submit that the panel's opinion affirming the lower court's ruling represents a dangerous development in the expansion of agency power. In the seventy plus years of the FDA's existence, there are no published opinions holding that the FDCA carries with it the power to order restitution. While our system of government depends on a flourishing regulatory apparatus, control of agency discretion is a core objective of administrative law theory and practice. Christopher F. Edley, Jr., Administrative Law: Rethinking Judicial Control of Bureaucracy 6 (1990). Unchecked agency discretion jeopardizes legitimacy in the administration of government and further raises serious concerns regarding the separation of powers. *Id.* at 215. It is Congress' prerogative to vest the FDA with the power to obtain restitution and had it so intended, the FDCA would clearly reflect that purpose.[1] For the Courts below to read

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[1] In *Massachusetts Mutual Life Ins. Co. v. Russell*, 473 U.S. 134, 147 (1985), this Court held that ERISA's breach of fiduciary duty provision, § 409(a), 29 U.S.C. § 1109(a), provided no express authority for an award of punitive damages to a beneficiary. In addition, this Court declined to find an implied cause of action for punitive damages in that section, noting that "[t]he presumption that a remedy was deliberately omitted from a statute is strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement." *Russell*, 473 U.S. at 147 (quoting *Northwest Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 97 (1981)). This Court's scrutiny of these ERISA policies made it "reluctant to tamper with an enforcement scheme crafted with such evident care as the one in ERISA." *Russell, supra*, 473 U.S. at 147. We submit that, in this case, Congress also enacted, in the FDCA, a comprehensive scheme that included an integrated system of procedures for enforcement. It simply should not be tampered with. There is no evidence that Congress intended to authorize additional remedies that it forgot to incorporate expressly. See

this remedy into the Act ignores the clear language of the Act; runs contrary to the Act's legislative history; transcends the judicial function; and creates a danger of unfettered agency power. "Although it is much too late to deny that there is a significant body of federal law that has been fashioned by the federal judiciary in the common-law tradition, it remains true that federal courts, unlike their state counterparts, are courts of limited jurisdiction that have not been vested with open-ended lawmaking powers." *Northwest Airlines, Inc.* v. *Transport Workers Union of America, AFL-CIO*, 451 U.S. 77, 95 (1981).

The FDCA is quite explicit in spelling out the remedies Congress envisioned should be available under its statutory scheme for violations of the statute. These remedies include (1) injunctive relief, 21 U.S.C. § 332; (2) criminal prosecution, 21 U.S.C. § 333; and (3) seizure, 21 U.S.C. § 334. The statutory scheme makes no provision for restitution. Interestingly, the Government requested disgorgement, not restitution, in its complaint and its motion for summary judgment. (R65: 2.)[2] The district court declined to award disgorgement because "neither the parties nor the court could find an FDA case where disgorgement of profits was ordered . . . [and] nonutilization does cast some doubt on the appropriateness of disgorgement in this matter." *See* Appendix B at 33a. Despite the absence of statutory authority and despite any express request for this relief by the FDA, the district court determined *sua sponte* that restitution was appropriate and available under the court's equitable powers. *Id.* at 34a. We submit that such ruling was erroneous and that the panel was wrong to affirm this ruling.

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also *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979) (holding that where a statute expressly provides a series of particular remedies, a court must be chary of reading others into it); see also *Touche Ross & Co. v. Redington*, 442 U.S. 560, 571-74 (1979).

[2] "R-" refers to the consecutively numbered items contained in the Record-On-Appeal below.

It is well settled that a statute may expressly or "by necessary and inescapable inference" restrict a court's equitable jurisdiction. *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291 (1960) (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 397-98 (1946)). The FDCA does precisely that. The FDCA provides a three-part framework for enforcement of its provisions, including injunctions, seizures and criminal prosecutions. Nowhere else in the FDCA are general remedies authorized, and the only mention of restitution in the entire FDCA occurs in a section dealing with clean up of clandestine methamphetamine sites, where the FDCA *explicitly* authorizes the imposition of restitution. 21 U.S.C. § 853. Additionally, while the FDCA's legislative history does not shed a great deal of light on Congress' position vis-à-vis the equitable remedies available under the Act, there are clear indications that Congress did not have an expansive view of the subject. The House Report notes: "The statute appears to provide adequate authority to clear the market of potentially dangerous or fraudulent products by seizure alone." H.R. Rep. No. 585, 920 Cong. 1st Sess. 3 (1971).

Although district courts are allowed to interpret incomplete statutory provisions, the authority to construe a statute is fundamentally different from the authority to provide a new remedy which Congress has decided not to adopt. *See Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625 (1978). The district court's decision not to order disgorgement because no case had previously done so but instead to award the greater penalty of restitution is simply bizarre. The only case to address restitution in an FDA action specifically found that the FDCA does *not* authorize restitution as a remedy and that a court's general equitable powers do not provide the authority to order restitution. *United States v. Parkinson*, 240 F.2d 918 (9th Cir. 1956). The *Parkinson* court held that "the use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms." *Id.* at 922. The holding is clear that unless the

statute specifically authorizes restitution as a potential remedy, the district court lacks jurisdiction to grant restitution in an action brought under the FDCA. There is simply no justification for treating congressional silence as the equivalent of a broad grant of remedial authority. The judiciary may not, in the face of a comprehensive legislative scheme, fashion a new remedy that upsets carefully considered legislative programs. *Northwest Airlines, Inc. v. Transport Workers Union of America, AFL-CIO*, 451 U.S. 77, 96 (1981).

Although the district court and circuit court of appeals opined that *Parkinson* was no longer good law because it was implicitly overruled by *Mitchell, supra*, we submit that such conclusion is erroneous. The court's reliance on *Mitchell* is misplaced. First, *Mitchell* was a Fair Labor Standards Act case that does not involve or mention the FDCA. Inasmuch as each statute has different goals, remedies that are appropriate for one statute may not be suitable for all statutes. Second, in *Mitchell*, this Court held that the grant of injunctive power in the Fair Labor Standards Act encompassed the power to order restitution of improperly withheld wages because such power created a vitally necessary incentive for employees to seek to enforce their rights by bringing their complaints to government officials. *Id.* at 292-93. A contrary ruling would face employees "with what is little more than a Hobson's choice" of seeking "restitution of partial deficiencies in wages due for past work perhaps obtainable only at the cost of irremediable entire loss of pay for an unpredictable period." *Id.* at 293. The FDCA creates no similar "Hobson's choice" because the statutory framework provides the FDA with more than sufficient means for enforcement of the FDCA without the ability to seek restitution.[3]

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[3] In *Mitchell*, this Court's holding that ordering reimbursements was within the power of the Fair Labor Standards Act was specifically predicated on the notion that the reimbursements in question were compensatory in nature. Compensatory restitution implies a benefit flowing to an individual

The district court ruling promoting the expansion of the FDA's power conflicts with a series of other district court decisions, such as *United States v. Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. 381 (E.D.N.Y.), *aff'd*, 72 F3d 285 (2d Cir. 1995), *United States v. Superpharm Corp.*, 530 F. Supp. 408 (E.D.N.Y. 1981), and *United States v. C.E.B. Products, Inc.*, 380 F. Supp. 664 (N.D.Ill.1974), all of which *restricted* similar attempts by the FDA to expand its available remedies beyond those set forth in the statute.[4] In each of these cases, the Government argued that Mitchell supported an expansion of its agency power. The FDA sought disgorgement in *Ten Cartons* and recalls in both *Superpharm* and *C.E.B. Products*. These courts uniformly held that *Mitchell* does not provide a basis for expanding the FDA's remedies and that the relief sought was neither available nor necessary to fulfill the purposes of the FDCA.

The *Superpharm* court addressed a request by the FDA to expand the remedies available in the context of FDA violations to include a recall. It closely reviewed the FDCA's legislative

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or entity in return for some harm previously suffered. Here, the record does not contain any evidence that the Stimulator does not work as intended, harms consumers in any way, or has any dissatisfied customers. It follows that the restitution granted in this case is not compensatory, but was in fact *punitive*, as evidenced by the trial court's desire to "send a message to both Defendants and others engaged in similar behavior that if they violate the law, they will not be able to keep the proceeds from such illicit activity . . ." *See* Appendix B at 35a. It is well-settled that courts of equity should not award punitive damages. *Tull v. United States*, 481 U.S. 412, 422 (1987). Yet, the lower court did just that in imposing restitution in this case.

[4] Petitioners acknowledge that the district courts are split on whether courts may use their general equitable powers to supplement the remedies available under the FDCA. *See, e.g., United States v. Barr Laboratories, Inc.*, 812 F. Supp. 458 (D.N.J. 1993) (holding that equitable remedy of a recall was available under the FDCA); *United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988 (N.D.Ill. 1978) (same); *United States v. Lanpar Co.*, 293 F. Supp. 147 (N.D.Tex. 1968) (same).

history, as well as *Mitchell*, and expressly rejected the FDA's attempt to expand the remedies available to it:

> The Government maintains that this court has the authority pursuant to section 302 of the Act, 21 U.S.C. § 332, to order a recall. . . . In addition, the Government contends that the court's general equitable power also authorizes issuance of a recall order. (Citing *Mitchell v. DeMario Jewelry, Inc.* 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960); *Porter v. Warner Co.*, 328 U.S. 395, 66 S.Ct. 1086, 90 L.Ed. 1332 (1945).) After examining both the case law and the Act's legislative history, it is quite apparent that there is little support for the Government's position. The prevailing law on the subject leads this court to conclude that no such statutory or equitable power exists, and that to order a recall would be an abuse and/or an improper use of its power.

530 F. Supp. at 409-10.

The court held that the FDCA provided sufficient means to enforce the Act, and that both the legislative history and text of the FDCA manifested "a reluctance to expand enforcement powers to the point where they are punitive." *Id.*

We submit that *C.E.B. Products* also demonstrates the continuing vitality of *Parkinson*. Its holding is instructive:

> Here, the government questions the continuing validity of *Parkinson* in light of the well-accepted proposition that a federal court, unless restricted by statute, may exercise the full range of equitable powers in support of its jurisdiction and in order to do complete justice in a particular case. Accordingly, plaintiff argues that, for this court "to do justice completely, and not by halves," *Camp v. Boyd*, 229 U.S. 530 (1913), a recall must be ordered.

380 F.Supp. at 669-70 (footnote omitted).

Like the FDA here, "Particular reliance [wa]s placed [by the government] upon *Mitchell v. Robert DeMario Jewelry, Inc.*," *Id.* at 670. After reviewing the relevant cases and the legislative history of the FDCA, the court rejected the Government's position:

> [I]n . . . *DeMario* . . . , the statutory interpretation adopted by the Court was consistent with the statutory language and policy, and the legislative history, and necessary to effective enforcement of the laws in question. [The] decision [] recognized, however, that a statute may expressly or "by necessary and inescapable inference" restrict a court's equitable jurisdiction. 361 U.S. at 291 []. Under those standards, this court has determined that its inherent equitable jurisdiction is not available to support the issuance of a recall order.
>
> It is clear that the FDCA establishes a specific, threefold enforcement scheme of injunctions, seizure, and criminal prosecutions. This system provides adequate before and after the fact remedies. . . . In seeking this recall, the government is asking for judicial sanction of an additional arrow for its already well-equipped bow. . . . Moreover, after studying the FDA's voluntary recall program, the aforementioned House subcommittee indicated its view on the efficacy of seizure by its statement that "the statute appears to provide adequate authority to clear the market of potentially dangerous or fraudulent products by seizure alone. . . ." H.R.Rep.No.585, 92d Cong., 1st Sess. 3 (1971)[] . . . .
>
> Thus, this court cannot conclude that "effective enforcement (of the Act) could. . . .only be expected," *Mitchell v. Robert DeMario Jewelry, Inc., supra* at 292 [], by interpreting section 302(a), or the statute in general and the circumstances surrounding its enactment, to allow the court to exercise its equitable powers to order a recall of

> adulterated products already on the market. This court is convinced that such an interpretation would constitute an unjustifiable judicial amendment of the FDCA. A review of the legislative history and statutory scheme can only lead to the conclusion that it was not the congressional purpose in the FDCA to empower courts to issue injunctions beyond prohibiting the violations specifically referred to therein.

380 F. Supp. at 671-72 (footnote omitted).

Finally, the *Ten Cartons* court rejected an FDA request for disgorgement of profits for FDCA violations based on *Mitchell* and noted the following:

> The Court finds the Government's reliance upon the cases to be inapposite. The application of the ruling in *Mitchell* to violations of the FDCA was rejected in *United States v. Superpharm Corp.*, 530 F. Supp. 408 (E.D.N.Y. 1981). . . . The court determined that the legislative history concerning the enforcement scheme set forth in sections 332-334 of the FDCA indicates that Congress intended seizures to be the most drastic remedy under the Act, and that injunctions were meant to alleviate the hardship of seizures to the manufacturer or distributors. *Id.* at 410. . . . The Superpharm court further held that *Mitchell* was distinguishable from the case before it, because in *Mitchell* the injunctive relief requested was required in order to accomplish the purpose of the legislation. . . . This Court believes the same considerations are applicable here to distinguish *Mitchell*. The purposes of the FDCA are served here by the FDA's seizure and the permanent injunction which will be issued in connection with the Court's Opinion. Disgorgement, in the Court's view, will only serve a punitive purpose and is not appropriate or necessary.

888 F. Supp. at 404 (other citation omitted).

The conclusion that the FDA may *not* obtain disgorgement of profits, because Congress intended seizures to be the most drastic remedy under the FDCA, means that the FDA similarly may *not* obtain restitution. The decisions below clearly conflict *inter alia* with both *Superpharm Corp.* and *Ten Cartons*. Congress has not taken a position on whether restitution is an appropriate remedy under the FDCA. We submit that the selection of remedies under the FDCA is a function more appropriate for those who write the laws than for those who interpret them. *See United States v. Gilman*, 347 U.S. 507, 511-13 (1954).

ARGUMENT 2

Holding Monea Jr. Liable Constitutes an Improper Extension of the *Dotterweich* Standards For Individual Liability Under the FDCA, In Violation Of Due Process

1. *Statement of Relevant Facts*

Monea Jr. was strictly an employee of UMS and had no affiliation with Natural Choice. (R98 at Exhibit K) The only government evidence as to Monea Jr. in the record was the declaration of an FDA agent, Frederick Lochner, filed with the FDA's motion for preliminary injunction. In a conclusory fashion, Mr. Lochner stated: "Mr. Monea, Jr. [wa]s in charge of the day-to-day activities of [UMS] during Mr. Monea, Sr.'s frequent absences and consult[ed] with Mr. Monea, Sr. on major decisions affecting the business." (R2 at Lochner Declaration ¶6) Mr. Lochner made similar statements at the summary judgment hearing in testifying that Paul A. Monea "was in charge of the daily operations [at UMS], and in that regard he would then answer to his father, who would have final responsibility or ultimate responsibility for the activities at the firm." (R36: 17.) There is no evidence that Monea Jr. owned any interest in either UMS or Natural Choice. There is no evidence that he made significant decisions that affected the direction of the corporate defendants or that he controlled the companies in any way. There is no evidence that he was aware of any of the

violations of the FDCA. Finally, there is no evidence that he had the power to correct the alleged violations had he been aware of them.[5]

2. *Analysis*

To uphold the district court's ruling that Monea Jr. should be held personally liable under the FDCA, the panel had to find, upon a full review of the record, that there was no genuine issue of material fact in the Government's case against him. The substantive standard of proof that had to be met is enunciated in *United States v. Dotterweich*, 320 U.S. 277 (1943), where this Court held that a finding of corporate guilt would extend only to those individuals who had a "responsible share in the furtherance of the transaction which the statute outlaws." *Id.* at 284. This standard was subsequently refined in *United States v. Park*, 421 U.S. 658 (1975), which required that the Government establish a *prima facie* case showing that the defendant failed to act on authority which could have prevented or corrected the violation. *Id.* at 673-74. A *prima facie* case may be established by introducing "evidence sufficient to warrant a finding by the trier that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." *Id.* The *Park* standards have only been used to find liable individuals who were *both* officers or owners of the companies in question *and* who had real power to correct the violation. *See United States*

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[5] In considering the appeal of the grant of summary judgment against Monea Jr., the circuit of appeals found that Petitioners had only appealed the imposition of summary judgment and not the subsequent denial of a motion for reconsideration. *See* Opinion at 8. As such, the circuit of appeals found that Monea Jr.'s challenge to summary judgment was waived. *Id.* We submit that conclusion was incorrect. Indeed, Petitioners' appeal from the December 1997 order was an appeal challenging the propriety of summary judgment as to Monea Jr., irrespective of the later motion to reconsider.

v. Starr, 535 F.2d 512, 515-16 (9th Cir. 1976) (finding, under *Park*, corporation's officer liable when he delegated responsibilities for complying with FDCA to an employee who failed to take proper action); *United States v. Torigian Labs.*, 577 F. Supp. 1514, 1529-30 (E.D.N.Y. 1984) (using *Park* standards, president and owner of controlling shares of corporation found personally liable for failing to use authority to detect, prevent, or correct FDCA violations); *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980) (applying *Park* to find that position as president is insufficient, by itself, to establish responsible relationship).

A close analysis of the record demonstrates genuine issues of material fact as to whether Monea Jr. had a responsible share in furthering the improper distribution of the Stimulator. Moreover, the record fails to show that he was aware of the violation or could have prevented the violation or could have convinced his father to comply with the law and correct the violation. As a result, we submit that it was error to hold him personally liable under the FDCA as a matter of summary judgment.

Although the panel found that UMS *and* Natural Choice were managed by both Monea Sr. and Monea Jr., *see* Appendix A at 2a, this conclusory statement is not based on any evidence or proof in the record. The Government's allegations and evidence with respect to Monea Jr. are simply that he was "in charge of the day-to-day activities of Universal during Mr. Monea, Sr.'s frequent absences and consult[ed] with Mr. Monea, Sr. on major decisions affecting the business." (R1: ¶6) The Government's proof comes from an FDA investigator, who reiterated the claim that Monea Jr. was consulted by his father on major decisions but did not have final authority on any substantial matter. (R2 at Lochner Declaration ¶6.) The investigator also testified at the summary judgment hearing, stating that Monea Jr. "was in charge of the daily operations [at UMS], and in that regard he would then answer to his father, who would have final responsibility or ultimate responsibility for the activities

at the firm." Despite this assertion, there is no evidence in the record of Monea Jr.'s involvement in management such as his signature on checks, his name on company letterhead or compensation other than his payroll check. There is certainly no evidence that, as an employee, albeit as the owner's son, he had authority to stop distribution of Stimulators.

Nevertheless, a panel of the Court of Appeals, in reviewing the district court's order, held that Monea Jr.'s role in the company was sufficient to subject him to injunction because "he maintained various forms of independent authority and responsibility." *See* Appendix A at 13A. This platitude could apply to all mid-level employees who are given any type of responsibility and it conflicts with the mandate of *Dotterweich* which focused on those "who have a responsible share in the furtherance of the transaction which the statute outlaws." In affirming the district court's decision, the panel relied on *United States v. Hodges X-Ray*, 759 F.2d 557, 560-61 (6th Cir. 1995). We submit that *Hodges X-Ray* is easily distinguished from the case at hand. Indeed, in *Hodges X-Ray*, the individual who was held personally liable for the alleged violations was the principal shareholder and president of the corporate defendant. This is simply not Monea Jr.'s situation.

The circuit of appeals' opinion wrongly extends the *Dotterweich* and *Park* standards for individual liability under the FDCA. Worse, it leaves all mid-level employees who have some degree of responsibility or authority in corporate entities that may be accused of violating the FDCA utterly unclear as to their duty under the Act. As a matter of public policy, this type of ambiguity and lack of notice is both discouraged and dangerous. When the legality of a person's conduct is challenged, this Court has declared that "[n]o one may be required at peril of life, liberty *or property* to speculate as to [the statute's] meaning. . . All are entitled to be informed as to what the State commands or forbids." *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939). Because of the serious consequences of vagueness in

criminal and quasi-criminal regulations, courts must construe them "rigorously in order to protect unsuspecting citizens from being ensnared by ambiguous statutory language." *United States v. Insco*, 496 F.2d 204, 206 (5th Cir. 1974). The principle of strict construction is enforced most vigorously when, as in the case of the FDA, Congress has delegated to an agency of the executive branch, the same branch of government entrusted with enforcement powers, the authority to determine how the penal sanctions should apply and what types of remedies should be used. *Diamond Roofing Co. v. OSAHRC*, 528 F.2d 645, 650 (5th Cir. 1976). *See also Kropp Forge Co. v. Secretary of Labor*, 657 F.2d 119, 122 (7th Cir. 1981) (approving the "traditional rule that the applicability of penal sanctions in regulations is to be narrowly construed by the judiciary").

It is well settled that where a law is vague or highly debatable, a defendant cannot be held to possess the requisite intent to violate the law. *United States v. Batcheler*, 442 U.S. 114, 123 (1979); *James v. United States*, 366 U.S. 213, 221-222 (1961); *United States v. Garber*, 607 F.2d 92, 98 (5th Cir. 1979); *United States v. Critzer*, 498 F.2d 1160, 1162 (4th Cir. 1974). Due process principles require that an individual be given fair notice as to what constitutes illegal conduct and an opportunity to conform his conduct to the requirements of the law. *See Colautti v. Franklin*, 439 U.S. 379, 390 (1979), *overruled in part on other grounds*, *Webster v. Reproductive Health Servs.*, 492 U.S. 490 (1989); *United States v. Dahlstrom*, 713 F.2d 1423, 1427 (9th Cir. 1983), *cert. denied*, 466 U.S. 980 (1984); *United States v. Curcio*, 712 F.2d 1532, 1543 (2d Cir. 1983); *Florida Businessmen for Free Enterprise v. City of Hollywood*, 673 F.2d 1213, 1218 (11th Cir. 1982). Even a regulation which governs purely economic or commercial activities, if its violation can produce penalties, must be so framed to provide adequate warning to those whose activities are governed. *See Diebold, Inc. v. Marshall*, 585 F.2d 1327, 1336 (6th Cir. 1978) (on review of decision of Occupational Safety and Health Re-

view Commission that employer had violated a safety provision, holding that the regulation had given insufficient warning to employer in view of inartful drafting of a safety regulation, in view of past industry practice, and in view of past enforcement history); *see also Joseph Seagram & Sons, Inc. v. Hostetter*, 384 U.S. 35 (1966), *overruled on other grounds, Healy v. Beer Inst., Inc.*, 491 U.S. 324 (1989).

Justice Holmes spoke of "fair warning. . . given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed." *McBoyle v. United States*, 283 U.S. 25, 27 (1931). In the case at hand, the panel decision abrogates this "clear warning." What should an employee in charge of shipping do when told by the company's owner to continue distributing a device that may be charged later as misbranded or adulterated under 21 U.S.C. §301? The panel's opinion offers absolutely no guidance in helping such employees to understand whether they are potentially liable under the FDCA. Moreover, it fails to provide an explanation for when employees may face injunction and potentially severe restitution obligations if they obey the orders of their company's owner or president. Worse, it utterly fails to address whether an employee to be liable must know of the FDCA violation and/or be able to correct it. As a result the panel ruling is the type of vague opinion that is not only disfavored but violative of due process rights. Simply stated, the panel decision as to Monea Jr. is wrong on the law and wrong on the facts.

CONCLUSION

The Court of Appeals' decision in this case ordering the remedy of restitution is an unwarranted extension of FDA powers under the FDCA, is inconsistent with both the Act and its legislative history, and is contrary to well-established authority in other Federal circuits. The standards for individual liability under the FDCA are ill-defined and were wrongly applied in this case. The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 98-3310

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

UNIVERSAL MANAGEMENT SERVICES, INC., CORPORATION;
NATURAL CHOICE, INC. CORPORATION,
doing business as Natural Choice Products, Inc.;
PAUL M. MONEA, individual; PAUL A. MONEA,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Ohio at Cleveland
No. 95-02768—Solomon Oliver, Jr., District Judge

Argued: August 10, 1999
Decided and Filed: September 13, 1999

Before: NORRIS and SUHRHEINRICH, Circuit Judges;
RICE, District Judge.*

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* The Honorable Walter H. Rice, United States District Judge for the Southern District of Ohio, sitting by designation.

OPINION

SUHRHEINRICH, Circuit Judge. Defendants appeal summary Judgment for plaintiff and a permanent injunction from the manufacture and sale of a device intended to relieve certain types of physical pain when applied to accupressure points. We AFFIRM.

The court of appeals reviews an order granting summary judgment de novo, and hence uses the same test as used in the district court. See *Terry Barr Sales Agency, Inc. v. All-Lock Co.*, 96 F.3d 174, 178 (6th Cir. 1996). Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

I.

Appellants Universal Management Services, Inc., and Natural Choice, Inc. are Ohio corporations which are managed by Appellants Paul M. Monea and his son, Paul A. Monea. As part of their business, Appellants sell and distribute a product known as the Stimulator, and also a product that connects to the Stimulator known as the Xtender. The Stimulator is essentially an electric gas grill igniter, marketed as a pain relieving device. To produce the Stimulator, Appellants purchase gas grill igniters and outfit them with finger grips. A user then places the tip of the Stimulator on his body, presses with his thumb on a plunger, and an electric current passes into that part of the body. Appellants' advertising literature states that, when applied to certain acupressure points, the Stimulator can relieve numerous kinds of pain (e.g., migraine headaches, swollen joints, allergies). J.A. at 76-77, 505, 808, 810, 814. The Xtender is an accessory that allows an individual to use the Stimulator to reach areas of the body otherwise difficult to reach,

such as the spine. In total, Appellants sold a total of 800,000 gas grill ignitors, at a cost to the company of one dollar each, for $88.30 each. J.A. at 505, 793, 839.

In May 1995, U.S. Marshals seized over $1.2 million worth of Appellants' devices pursuant to seizure authority under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA). J.A. at 782-84. Later that month, the Food and Drug Administration (FDA) informed Appellants that they considered the devices adulterated and subject to regulation, threatening further legal action if approval was not sought and distribution did not cease. J.A. at 78. Distribution did not cease and the Government sought the injunction that is the subject of this appeal. The district court granted summary judgment for the Government on December 30, 1997, and, in February 1998, rejected Appellants' Motion for Reconsideration. J.A. at 774-75. The resulting judgment placed a permanent injunction against the distribution of Appellants' products and ordered Appellants to offer full refunds to all customers who had purchased their devices after the May 1995 seizure. J.A. at 39, 50.

II.

The district court concluded that the Stimulator and Xtender are "adulterated" devices under the FDCA. Specifically, the Government claims that Appellants violated 21 U.S.C. § 331 (a) and § 331(k), which prohibit misbranding or adulterating medical devices and introducing such devices into interstate commerce.

To show a violation of § 331(a) and (k), the Government must prove: (1) Appellants' products are "devices" within the meaning of the FDCA; (2) the devices are adulterated or misbranded; and (3) the devices move in interstate commerce. The third element is undisputed.

A device is "adulterated" under the FDCA if it is required to receive premarket approval ("PMA") from the FDA but moves in commerce even though it did not receive this PMA. See 21

U.S.C. § 351(f)(1)(B); *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F.Supp. 990, 998 (W.D. Mich. 1985). Whether a device is required to receive a PMA from the FDA depends on a scheme set out in 21 U.S.C. § 360c. Under this scheme, all medical devices are categorized as Class I (minimal regulation), Class II (intermediate regulation), or Class III (stringent regulation) devices. All "new devices," those not on the market before 1976, are, as a default, automatically Class III devices.

Class III devices cannot be marketed unless either: (1) the manufacturer has submitted to the FDA an application for a PMA and receives approval; or (2) the manufacturer submits a "premarket notification" arguing that its device should be reclassified as Class I or II because it is substantially equivalent to an existing device so categorized and the FDA finds the devices are in fact so equivalent.

Appellants contend that their products[1] are not violative of §§ 331(a) & (k) for three reasons. First, they argue their products are not devices within the meaning of the FDCA. The FDCA's definition of "device" is as follows:

> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is . . .

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[1]Both parties focus their analysis on the Stimulator when debating coverage under the FDCA's definition of a device. Appellants fail to present this court with a distinction between the XTender and the Stimulator. The argument might be made that the XTender is merely an accessory to the Stimulator, sold separately, and does not independently satisfy the definition of "device." This court, however, will not speculate as to the factual or legal basis for such a claim. Because Appellants speak of their product as a singular entity, failing to distinguish between their functions or coverage under the FDCA, this court must treat them as such. See *United States v. Maliszewski*, 161 F.3d 992, 1015 (1998) (issue not raised in the district court or briefed to Court of Appeals could not be considered on appeal).

> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intending to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h).

Appellants claim that their products are not devices because they (1) achieve their primary intended purpose through chemical action and (2) do not have any effect on the structure or function of the body. As the district court found, however, Appellants presented no genuine issue of material fact that their products operate through chemical action, and two of their own witnesses, Dr. Roy Bugay and Dr. Robert Charm, both indicated that their products do not operate through chemical action. J.A. at 34. The district court also noted that Appellants pointed to nowhere in the record to establish that their products have no effect on the structure or function of the body.[2]

We agree with the district court. Appellants' own description of the products supports the Government's position. Appellants describe the Stimulator, for example, as working as follows: "the [] electrical stimuli [from the device] . . . stimulate excitatory cells which release electrical potentials which set off a chain of . . . reactions that send messages to the brain creating a responsive reaction that organizes peptides to return the body

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[2] Moreover, if Appellants are correct that the Stimulator operates through chemical action, it would likely be subject to regulation as a drug or drug delivery device under FDCA. *See*, e.g., 21 U.S.C. §§ 321(a), 355(a), 352(a).

to homeostasis." J.A. at 34. Appellants also assert their product relieves pain. As such, the products are intended to affect the function of the body and are, therefore, devices under 21 U.S.C. § 321(h)(3)[3].

III.

In their Motion for Reconsideration, Appellants raised two issues not originally presented to the district court. First, Appellants claim that it was entitled to a new trial given the malfeasance of Appellants' original trial counsel. Second, Appel-

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[3] Alternatively, Appellants asserted below that their device is similar to a device marketed before 1976, thereby obviating the need for PMA. The district court concluded, however, that Appellants made only a conclusory claim to support this and pointed to no specific record evidence in support.

Appellants also claim that their product is not subject to a PMA because it is exempt from FDA approval. This argument is based on the contention that the Stimulator is identical to another device, the "Accu-Magic," which is considered a Class I device and is "listed" with the FDA as a therapeutic massage device — a class of products exempt from the premarket clearance requirement of the Medical Device Amendments to the FDCA. The device listing requirement, 21 U.S.C. § 360(j), is a means by which the FDA keeps a current inventory of devices marketed in the United States. The Government, however, presented a letter from the FDA to the manufacturer of Accu-Magic informing it that its device is not a therapeutic massager and that it is not exempt. J.A. at 36. Therefore, reference to Accu-Magic alone does not establish an exemption for the Stimulator. Moreover, as a Class III device, the FDCA requires a PMA or a finding by the FDA of substantial equivalence before a manufacturer may bring the product to market. See 21 U.S.C. § 360c(i); *United States v. One Unlabeled Unit . . . Thor of Genesis*, 885 F.Supp. 1025, 1028 (N.D. Ohio 1995). Neither was obtained in this case.

Neither argument presented above is made on this appeal as a means of illustrating the FDA lacked authority to regulate Appellants' product. Each, however, is presented as evidence that Appellants' violation was minor and should not have warranted an order of restitution. That subject is discussed in Section V of this Memorandum.

lants claim that Paul A. Monea may not be personally subject to an injunction.

A.

The Notice of Appeal in this case, however, indicates that Appellants are appealing only from the district court's order granting summary judgment to the Government and the denial of their motion for summary judgment. Appellants fail to appeal from the district court's denial of their Motion for Reconsideration. J.A. at 55. Therefore, Appellants are foreclosed from asking this court to review the issues rejected in the district court's denial of their Motion for Reconsideration because the general rule is that "[i]f an appellant . . . chooses to designate specific determinations in his notice of appeal—rather than simply appealing from the entire judgment—only the specified issues may be raised on appeal." *McLaurin v. Fischer*, 768 F.2d 98, 102 (6th Cir. 1985). However, the Government addresses the merits of the Motion for Reconsideration issues raised on appeal because, it argues, absent a showing of prejudice, this court has usually considered such an error in what is appealed to be harmless. *See id.* This is inaccurate.

The court must always consider its jurisdiction first and may not hear a cause over which it has no jurisdiction. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, ___, 118 S. Ct. 1003, 1012-13 (1998). Federal Rule of Appellate Procedure 3(c)(1)(B) requires the designation of the judgment or order from which an appeal is taken. Moreover, this rule is jurisdictional and may not be "waived" by this court. *See Torres v. Oakland Scavenger Co.*, 487 U.S. 312, 317 (1988); *Smith v. Barry*, 502 U.S. 244, 248 (1992) ("Rule 3's dictates are jurisdictional in nature, and their satisfaction is a prerequisite to appellate review.") (citing *Torres*, 487 U.S. at 316-17). *Cf. Dillon v. United States*, No. 97-3138, 1999 WL 511697 (6th Cir. July 21, 1999) (en banc) (although Rule 3 is jurisdictional in nature, mere errors in form will not always preclude juridiction). The Court in *Torres* cautioned, "although a court may

construe the Rules liberally in determining whether they have been complied with, it may not waive the jurisdictional requirements of Rules 3 and 4, even for 'good cause shown' under Rule 2, if it finds that they have not been met." *Torres*, 487 U.S. at 317. *See also Maerki* v. *Wilson*, 128 F.3d 1005, 1007 (6th Cir.1997) ("The requirements of Rule 3(c) are jurisdictional in nature, and the court of appeals may not waive or diminish the rule's requirements."); *Minority Employees v. Tennessee Dep't of Employment Sec.*, 901 F.2d 1327 (6th Cir. 1990) (en banc) (appellant's failure to satisfy the requirements of Rule 3(c) is fatal to his appeal); *Mattingly*, 153 F.3d at 337 (Rules 3 and 4 are jurisdictional and appellant's failure to sign the notice of appeal pursuant to Rule 4(a)(1) was fatal to the appeal).

"[L]itigants are charged with the responsibility for complying with the Federal Rules of Appellate Procedure." *Maerki*, 128 F.3d at 1008. We cannot excuse noncompliance. *Torres*, 487 U.S. at 317. "Rather plainly, certain rules are deemed sufficiently critical in avoiding inconsistency, vagueness and an unnecessary multiplication of litigation to warrant strict obedience even though application of the rules may have harsh results in certain circumstances. Under *Torres*, Rule 3(c) is such a rule." *Minority Employees*, 901 F.2d at 1329. Because the notice of appeal references only the district court's summary judgment rulings, we do not have jurisdiction to consider issues raised in the Motion for Reconsideration.

B.

In so far as we would be required to consider the merits of the issue of malfeasance of counsel as properly appealed, we find no reversible error. This court reviews the district court's denial of the Rule 60(b) motion for an abuse of discretion. *See Hood v. Hood*, 59 F.3d 40, 42 (6th Cir. 1995).

Appellants argue that the district court erred in denying their Motion for Reconsideration because, they contend, the alleged wrongdoing of their former counsel, Edwin Davila, provides

grounds under Federal Rule of Civil Procedure 60(b) for relieving them of the district court's summary judgment order against them. Rules 60(b)(1)-(5) provides relief for mistakes, inadvertance, excusable neglect and other similar situations. Rule 60(b)(6) is a catch-all provision that should be granted only when the movant demonstrates "extraordinary circumstances." See *Liljeberg v. United States*, 486 U. S. 847, 863-64 (1988).

The "malfeasance" that Appellants allege is essentially that Mr. Davila: (1) committed crimes (stole money, created a fictitious lawsuit, and stole a car); (2) refused to return files to them; (3) engaged in various misdeeds in the district court proceedings (copied from a law review article, a case, and a Federal Register notice; filed videotapes instead of written affidavits; failed to serve Government counsel; and taped a telephone conversation without the knowledge of all parties); and (4) inadequately represented them by making a frivolous argument, not conducting discovery, and failing to argue that an individual cannot be enjoined unless he was a "high managerial agent" who "knew that his actions violated the FDCA."

Davila ceased representing the Appellants in August, 1997, and a new attorney, Ralph Burns, took over their representation at that time. J.A. at 459. The district court formally admitted Burns to the case in September 1997. J.A. at 461. Appellants had the opportunity, through Burns, to bring these allegations of malfeasance to the district court's attention prior to final judgment. In fact, Burns moved successfully to reopen summary judgment on the issue of disgorgement in September 1997. J.A. at 470, 481. There is no evidence he would have been unable to similarly correct any other legal errors by Davila. Appellants began to discover the alleged malfeasance at least as early as August 1997, four months before the district court issued its summary judgment order. J.A. at 763. They filed their six complaints against Davila with the Ohio bar in October, two months before entry of summary judgment. J.A. at 832-934. In fact, prior to summary judgment, Burns chose to

inform the district court of the substance of one of the complaints to the bar. J.A. at 487. He could have informed the district court of the remaining issues, allowing the district court an opportunity to give Appellants additional means for correcting any errors of Davila.

There is also no evidence that Appellants ever sought an order compelling Davila to return the missing files. Burns could have sought a stay and could have himself sought the discovery of the materials Appellants claim Davila should have sought.[4] Burns was not without opportunity to seek these methods of relief or correction, for he interacted with and appeared before the district court on numerous occasions prior to entry of summary judgment. J.A. at 464, 462-63, 11, 493, 786. There was no reason to disrupt the finality of the district court's judgment when Appellants had an opportunity to overcome the errors of Davila.

Moreover, Appellants have failed to establish prejudice from the malfeasance. There is no evidence presented that the crimes alleged against Davila are relevant to the merits of this case. Appellants do not identify anything in the missing files that could change the case.[5] The misdeeds before the district court are also not tied to the district court's decision. Appellants did not lose based on any procedural errors but instead lost on the merits. They also fail to tie Davila's frivolous arguments to any prejudice. Finally, Appellants do not identify any issues on which further discovery could have led to evidence that could have affected the outcome of the case.

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[4] In fact, there is evidence Burns contemplated doing so but apparently decided against it. J.A. at 459.

[5] Although they mention a study that they claim relates to substantial equivalence of the Stimulator to another device, "substantial equivalence" is a judgment for the FDA, not the courts, and therefore the absence of that study is not relevant to the courts' decisions.

The issues in this case were fully briefed and decided on the merits by the district court.[6] Because Appellants had ample opportunity to cure the effects of the malfeasance prior to entry of summary judgment and, alternatively, because they cannot show any prejudice from the errors or misdeeds of counsel, the district court was not faced with any enumerated rationale under Rule 60(b) nor was it faced with "extraordinary circumstances" justifying a disruption of the finality of the district court judgment. Therefore, it did not abuse its discretion by denying Appellants' Motion for Reconsideration.

C.

In their Final Brief, Appellants argue that Paul A. Monea cannot be enjoined individually because he is not a covered individual for such liability under 21 U.S.C. § 335a(b). In their Reply Brief, Appellants contend that, even if § 335a(b) does not preclude enjoining Paul A. Monea, general principles of equitable injunctions prevent subjecting him to such action.

Even assuming the issue of enjoining Paul A. Monea were properly noticed in the notice of appeal, Appellants face additional obstacles preventing this court from reaching the merits of that claim. The Government contends that Appellants' argument, that Paul A. Monea cannot be enjoined individually because he was not a "high managerial agent" with knowledge that he was violating the FDCA as required for such liability under 21 U.S.C. § 335a(b), was never presented to the district court and, therefore, cannot be considered by this court. *Bailey*

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[6] The two cases primarily relied upon by Appellants, *United States v. Cirami*, 563 F.2d 26 (2d Cir. 1977), and *Boughner v. Secretary of HEW*, *572 F.2d 976* (3d Cir. 1978), are inapposite. In each, counsel failed to respond to the Government's motion for summary judgment. The courts of appeals reversed the denial of the motions for reconsideration so that the merits of the cases could be considered. Here, the district court's entry of summary judgment was not based on Appellants default, and it entered such based on the merits.

v. Floyd County Bd. Of Educ., 106 F.3d 135, 143 (6th Cir. 1997). It is correct. Because the issue was not raised in the district court below, Appellants have waived their right to argue the point on appeal. See *White v. Anchor Motor Freight, Inc.*, 899 F.2d 555, 559 (6th Cir. 1 990) ("This court will not decide issues or claims not litigated before the district court."); *Thurman v. Yellow Freight Systems, Inc.*, 97 F.3d 833, 835 (6th Cir.1996) (claims not raised before the district court must be considered waived); *Lillard v. Shelby County Bd. Of Educ.*, 76 F.3d 716, 729 (6th Cir. 1996) (argument not raised before the district court is not properly before us). The Government's Complaint named all of the parties and included a prayer for injunctive relief against those parties. Appellants were put on notice, therefore, that the Government intended to seek such relief against Paul A. Monea and should have made any objection to the availability of such relief at trial.

Alternatively, in their Reply Brief, Appellants contend that whether or not the Government is correct in its contention that § 335a(b) is inapplicable in this case, the standard for a civil penalty against an individual must be high, requiring more than mere employment, and Paul A. Monea was not subject to injunction because he was not a responsible corporate agent. Just as their argument regarding § 335a(b) was waived, this argument is similarly waived, having not been presented to the district court. *See White*, 899 F.2d at 559. Furthermore, the issue regarding general liability for corporate agents is independently waived, having been raised for the first time in Appellants' Reply Brief. *See Wright v. Holbrook*, 794 F.2d 1152, 1156-57 (6th Cir. 1986).

2.

In so far as we would be required to consider the argument regarding Paul A. Monea's individual liability as properly appealed, it is also without merit. First, § 335a(b) does not apply to this case. That section concerns the wholly unrelated

issue of debarment of individuals for misconduct relating to the development and approval of generic drug products. *See, e.g., Bae v. Shalala*, 44 F.3d 489 (7th Cir. 1995). It neither relates to devices nor addresses injunctions.

Second, even the new argument in the Reply Brief relying on general principles is unhelpful to Appellants. According to statements of FDA investigator Frederick Lochner and Paul A. Monea himself, Paul A. Monea was in charge of managing day-to-day activities, J.A. at 780-81, and had supervisory responsibilities. J.A. at 717. Undisputed evidence indicates that he supervised shipping, inventory, and customer service. This role is sufficient to subject him to injunction. *See United States v. Dotterweich*, 320 U.S. 277, 281-84 (1943) (in violations of public health legislation like the FDCA, "[t]he offense is committed . . . by all who have a responsible share in the furtherance of the transaction which the statute outlaws."); *United States v. Park*, 421 U.S. 658, 672 (1975) (same). It cannot be contested on this record that Paul A. Monea was responsible for causing the introduction of Appellants' unlawful products into commerce, and continued such involvement without any effort to come into compliance with the FDCA even after Appellants' products were seized and the FDA undeniably notified Appellants of the need to obtain FDA approval. *See United States v. Hodges X-Ray*, 759 F.2d 557, 560-61 (6th Cir. 1985) (applying the *Park* and *Dotterweich* standards in finding an individual personally liable for civil penalties under a statute related to the FDCA). Appellants' argument that Paul A. Monea reported to his father is unavailing. Whether the father had ultimate authority is not the issue. All evidence regarding Paul A. Monea's involvement indicates he maintained various forms of independent authority and responsibility regardless of his father's role. This is sufficient to show that Paul A. Monea shared responsibility for the business process resulting in unlawful distribution and could, therefore, be held criminally liable or liable for civil penalties. *See United States v. Dotterweich*, 320

U.S. 277, 281-84 (1943). Similarly, his role is sufficient to subject himself to injunction, as in this case.

IV.

Below, the Government requested its costs and any such other relief the court deemed proper including equitable disgorgement of profits.[7] J.A. at 26-27. After finding disgorgement inappropriate, the district court found that restitution was a remedy available to the FDA and appropriate. The district court awarded restitution, finding that the FDCA does not contain a clear command indicating that restitution is not a remedy available to the district court. It supported its decision on the premise that the FDCA should receive liberal construction. *See United States v. An Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The restitution ordered required Appellants to offer and provide refunds to all of their customers who requested them in writing. J.A. at 50. Appellants challenge the restitution order, arguing the FDCA does not permit restitution and, if it does, restitution was inappropriate in this case.

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[7] Appellants originally claimed that the Government never requested restitution and that, as such, the court should not have ordered the same *sua sponte*. However, as counsel for Appellants conceded during oral argument, the Government's request for "any other such relief" is sufficiently broad language so as to include restitution within its scope. Federal Rule of Civil Procedure 54(c) provides that, "[e]xcept as to a party against whom a judgment is entered by default, every final judgment shall grant the relief to which the party in whose favor it is rendered is entitled, even if the party has not demanded such relief in the party's pleadings." As this court has recognized, this rule allows a district court to order restitution in an appropriate case even when it has not been requested in the Complaint. *See Shearson/American Express, Inc. v. Mann*, 814 F.2d 301, 307 (6th Cir. 1987) (prayer for "such further legal and equitable relief to which Shearson may be entitled" authorizes a district court to order restitution); *Dann v. Studebaker-Packard Corp.*, 288 F.2d 201, 216 (6th Cir. 1961) (a plaintiff in equity "is entitled to any relief appropriate to the facts alleged in the bill and supported by the evidence, even where he has not prayed for such relief").

A.

The FDCA provides only three remedies for violations: (1) injunctive relief, 21 U.S.C. § 332; (2) criminal prosecution, 21 U.S.C. § 333; and (3) seizure, 21 U.S.C. § 334. To rule on Appellants' first contention, that the FDCA does not permit orders of restitution, we must consider the scope of injunctive relief authorized under § 332.

The district court in this case was sitting as a court of equity. See 21 U.S.C. § 332(a) (granting the district court jurisdiction to restrain violations of FDCA). Restitution and disgorgement are part of courts' traditional equitable authority. *See Mertens v. Hewitt Ass'n*, 508 U.S. 248, 255 (1993) (ERISA does not limit available equitable relief); *Porter v. Warner Holding Co.*, 328 U.S. 395, 402 (1946); *Heinicke v. Parr*, 168 F.2d 194, 197 (6th Cir. 1948) ("[N]othing is more clearly a part of the subject matter of an injunction suit than the recovery of that which has been illegally acquired and which has necessitated injunctive relief."); *Schwartz v. Gregori*, 45 F.3d 1017, 1022-23 (6th Cir. 1995) (back pay awarded for retaliatory discharge constituted restitution and was, therefore, an equitable remedy available under ERISA); *Federal Trade Commission v. Gem Merchandising Corp.*, 87 F.3d 466, 469 (11th Cir. 1996) ("Among the equitable powers of a court is the power to grant restitution and disgorgement."); *Federal Trade Commission v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991) (restitution); *Federal Trade Commission v. Amy Travel Services, Inc.*, 875 F.2d 564, 570 (7th Cir. 1989) (restitution); *SEC v. Blatt*, 583 F.2d 1325, 1335 (5th Cir. 1978) (disgorgement).

Absent a clear command by Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised by the courts. In *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946) (in analyzing Emergency Price Control Act of 1942), the Supreme Court established that "[u]nless otherwise provided by statute, all the inherent equitable powers of the

District Court are available for the proper and complete exercise of that jurisdiction." *Id* at 398. *Porter* held that restitution "is within the recognized power and within the highest tradition of a court of equity." *Id* at 402. *See also Division No. 1, Detroit, Brotherhood of Locomotive Engineers v. Consolidated Rail Corp.*, 844 F.2d 1218, 1226 (6th Cir. 1988) (citing *Porter* in finding that Railway Labor Act does not alter courts' equitable powers). The court should "not interpret a statute as limiting the equitable jurisdiction of federal courts absent a clear command from Congress to the contrary." *Hadix v. Johnson*, 144 F.3d 925, 936 (6th Cir. 1998) (citing, among others, *Porter* in determining that Prison Litigation Reform Act's automatic stay provision should be construed to permit courts to retain their equitable power to suspend stay in accordance with general equitable principles).

This court has made it clear that, if "review of the . . . statute and its accompanying legislative history fails to reveal a clear congressional intent to displace the equitable powers of the federal courts, [the court] must construe the [statute] as preserving the courts' inherent power." *Hadix*, 144 F.3d at 936-37; *Heinike*, 168 F.2d at 197 ("the comprehensiveness of equity jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command").

A contrary standard upon which Appellants rely, that the statute must explicitly authorize restitution, was accepted by the Ninth Circuit in *United States v. Parkinson*, 240 F.2d 918 (9th Cir. 1956). This approach, however, was rejected by the U.S. Supreme Court in *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 290-92 (1960) (interpreting Fair Labor Standards Act).[8] *DeMario* held the following:

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[8] Other courts have also recognized that *Parkinson* was no longer good law after *DeMario*. *See, e.g., ICC v. B&T Transportation Co.*, 613 F.2d 112, 1184-86 (1st Cir. 1980) (rejecting *Parkinson* and *Porter* is settled law).

> The court below took as the touchstone for decision the principle that to be upheld the jurisdiction here contested "must be expressly conferred by an act of Congress or be necessarily implied from a congressional enactment. In this, the court was mistaken. The proper criterion is that laid down in *Porter v. Warner Holding Co.* . . . . When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of statutory purposes.

DeMario, 361 U.S. at 290-92 (citation omitted). The citation in *DeMario* to *Porter*, as well as this circuit' s acceptance of the *Porter* approach in *Hadix*, illustrates that Appellants' argument should be rejected. Notably, the *DeMario* Court also recognized that a district court's equitable powers are even broader and more flexible when the public interest is involved, as here. *DeMario*, 361 U.S. at 291 (quoting *Porter*, 328 U.S. at 398).

Appellants also rely on a number of district court cases that determine that recalls and disgorgement are unavailable under the FDCA. *See United States v. C.E.B. Prods., Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974) (recalls); *United States v. Superpharm Corp.*, 530 F.Supp. 408 (E.D.N.Y. 1981) (recalls); *United States v. Ten Cartons, Ener-B Nasal el*, 888 F.Supp. 381 (E.D.N.Y. 1995) (disgorgement), *aff'd on other grounds*, 72 F.3d 285 (2d Cir. 1995). Portions of the legislative history relating to the FDCA indicates that Congress was concerned about the harshness and seriousness of the remedy of seizure. *See, e.g.*, 74 Cong. Rec. 150 (1935); 74 Cong. Rec. 4915 (1935); S. Rep. No. 74-361, at 11 (1935). Injunctive procedures, it is argued, "were viewed as a means to alleviate the hardships seizures might cause to manufacturers." *C.E.B. Prods.*, 380 F.Supp. at 668. *See also Superpharm* (following the reasoning of *C.E.B. Products*); *Ten Cartons*, 888 F.Supp. at 404-05 (following *Superpharm*). Based on that legislative history, the court in *C.E.B. Products* reasoned that a recall

provision was probably not within the court's power because it would, in the court's opinion, make an injunction as harsh as a seizure, contrary to the intent of Congress. *See C.E.B. Prods.* 380 F. Supp at 668. Other district courts, however, have rejected this line of reasoning. *See, e.g., United States v. Barr Laboratories, Inc.*, 812 F. Supp. 458, 489 (D.N.J. 1993); *United States v. K-N Enterprises, Inc.*, 461 F. Supp. 988, 991 (N.D. Ill. 1978). *See also United States v. Tri-Bio Laboratories, Inc.*, 700 F.Supp. 223, 225 (M.D. Pa. 1988) (without exercising the power, finding that the court possessed "inherent equitable powers" to order the defendants to bear the costs of FDA inspections); *United States v. Lit Drug Co.*, 333 F. Supp. 990, 997-1000 (D.N.J. 1971) (calling for, among other remedies, recall of adulterated and misbranded drugs); *United States v. Lanpar Co.*, 293 F.Supp. 147, 155 (N.D. Tex. 1968) (requiring defendant to recall and destroy illegal products and related literature).

We reject the holdings in the *Parkinson* and *C.E.B. Products* line of cases. First, the existence of the remedy of seizure exists alongside an explicit authorization for injunctive relief to cure violations of the FDCA. The express provision for general equitable relief without the enumeration of any exceptions makes it difficult for this court to find any legitimate means for implicitly carving out such exceptions as we see fit. Even if Congress expressed some concern that seizure should remain the harshest relief available, there is no convincing argument that, in all cases, restitution creates a more harsh result than seizure, procedurally or substantively. Moreover, even accepting the references to legislative concerns relied upon by the *Parkinson* and *C.E.B. Products* line, these concerns are far from a clear statement of Congress's intent to exclude restitution, recalls, disgorgement, or any other traditional form of equitable relief. Finally, as *DeMario* instructs, we must presume that Congress is cognizant of the scope of equity, knows what it is doing when it provides for general equitable relief in a regulatory statute, and can use that knowledge to clearly and

explicitly limit the scope of a court's equitable powers under any particular regulatory structure in which such an authorization lies. *See DeMario*, 361 U.S. at 292.

Appellants have not established that the FDCA by "a necessary and inescapable inference, restricts the court's jurisdiction in equity." *DeMario*, 361 U.S. at 291. Nothing in the FDCA explicitly precludes a district court from ordering restitution. To find that restitution is unauthorized, this court "require[s] Congress to make plain its desire to limit the courts' inherent powers because 'the great principles of equity, securing complete justice, should not be yielded to light inferences or doubtful construction.'" *Hadix*, 144 F.3d at 937 (quoting *Porter*, 328 U.S. at 398). Appellants have not demonstrated that the FDCA or its legislative history "compels a departure from the courts' inherent power to achieve equity." *Hadix*, 144 F.3d at 938. Therefore, we hold that nothing in the FDCA precludes a court sitting in equity from ordering restitution in appropriate cases.

B.

Next, we must determine whether restitution was an appropriate remedy on the facts of the case at bar. We review an award of restitution for an abuse of discretion. *Secretary v. Johnston*, 143 F.3d 260, 262 (6th Cir. 1998).

Appellants first argue that the FDA's charge itself should preclude restitution. The FDA charge, they claim, was only that Appellants marketed a product without required approval, rather than that the product didn't perform as it was intended. If the performance is not questioned and no deficiency in the same is established, they contend that there has been no detriment to consumers justifying the restitution order. In other words, Appellants contend that restitution was unwarranted because there is no evidence that consumers received anything less than what they bargained for.

The approval process exists to protect consumers' health and their pocketbooks. One of the primary goals of the FDCA is to

protect consumers from economic harm. *See* H.R. Conf. Rep. No. 74-2755, at 1 (1938) (one purpose is to prevent "deceit upon the purchasing public"); *United States v. An Article . . . Sudden Change*, 409 F.2d 734, 740 (2d Cir. 1969) ("A primary purpose of the Act is the protection of the ultimate consumer's economic interests.") (citing *Federal Security Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230 (1943); *United States v. Two Bags . . . Poppy Seeds*, 147 F.2d 123, 126-27 (6th Cir. 1945)). It is not the government's burden to prove that a product is not safe and effective. FDCA regulations exist to allow the public to assume that marketed devices have received the imprimateur of FDA approval. To circumvent the law by marketing illegally without approval is to deceive the public both as purchasers and users of the device. In such case, restitution exists to make the consumer whole. *See First Penn Corp. v. Fed. Dep. Ins. Corp.*, 793 F.2d 270, 272 (10th Cir. 1986) (object of restitution is " to return the parties to the position that existed before the transaction occurred."). Because restitution seeks to remedy the type of economic harm to consumers contemplated by the FDCA, it serves goals of the FDCA that are encompassed within the section the FDA charges Appellants violated.

Appellants claim that the order of restitution was inappropriately punitive is also without merit. Appellants contend that the district court's statements that the ruling would "send a message" to deter future violations indicates a punitive intent, contrary to the purposes of restitution. The statement, however, merely emphasizes the deterrent effect of the order, an effect consistent with the FDCA's purpose in protecting the public health. "Future compliance may be more definitely assured if one is compelled to restore one's illegal gains." *Porter*, 328 U.S. at 400. Restitution is not a penalty but instead an award for the benefit of the consumer. *See Woods v. Witzke*, 174 F.2d 855, 856 (6th Cir. 1949); *DeMario*, 361 U.S. at 293 (restitution is not punitive because "the measurement of reimbursement is compensatory only"); *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 171-72 (1948) (not punishment to require

defendants return what they unlawfully obtained). Restitution is directed to "restoring the status quo and ordering return of that which rightfully belongs to the purchaser." *Porter*, 328 U.S. at 402. Thus, both by its nature and in this case, an order of restitution is not punitive where the offender has violated the law at the expense of the very consumers a restitution order seeks to make whole.

Appellants also claim that restitution is punitive because, unlike disgorgement which removes ill-gotten gain by forcing surrender of profits, restitution requires a return of the entire purchase price, included in which are costs and profits. *See Sec. Exch. Comm'n v. Blatt*, 583 F.2d 1325, 1335 (5th Cir. 1978) ("The purpose of disgorgement is not to compensate the victims of the fraud, but to deprive the wrongdoer of his ill-gotten gain."). *See also Sec. Exch. Comm v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90, 102 (2d Cir. 1978). Simply because disgorgement and restitution are different, however, does not make restitution punitive. *See SEC v. World Gambling Corp.*, 555 F.Supp. 930, 934 (S.D.N.Y.), *aff'd*, 742 F.2d 1440 (2d Cir.1983) ("[W]hile disgorgement has been said to serve more important interests than the compensation of investors, that principle is a far cry from the proposition that restitution is an improper end." (internal citation omitted)). Appellants, who disobeyed the law, should not have his expenses covered by consumers. To say that restitution is unavailable is to say that consumers must cover the costs of Appellants' production, advertising, and illegal distribution. Instead, the district court should have the discretion in a case such as this to make the consumers whole rather than allow the illegal activities to stand uncorrected to the consumer's detriment.

Despite Appellants' contentions, their violation was also more than a mere technicality. Congress set up a sophisticated statutory scheme for the regulation of medical devices, and the requirement that devices be approved or cleared by the FDA before marketing is at the heart of the scheme. *See* H.R. Rep. No. 94-853, at 14 (1976). Thus, Appellants' failure to achieve

such clearance violates a key component of the regulatory scheme. And, in the context of public health and safety, the district court's equitable authority is broader and more flexible to support such a regulatory scheme than in ordinary litigation.

The district court did not abuse its discretion in determining restitution was appropriate in this case. The district court seemed to fairly balance the equities in the case. There is evidence that Appellants continued to distribute their product without seeking any approval even after they were put on notice of their violation by the FDA in May 1995, J.A. at 91-92, distributed after district court issued a preliminary injunction, J.A. at 323-25, and obstructed FDA inspections, J.A. at 252, 309-10, 288-89, 281-82. Appellants were hardly mere flies caught in the web of technical government regulation. Appellants marketed a device to the consuming public, a public that the FDCA regulatory structure seeks to protect. Appellants marketed their product in clear violation of the FDCA. They continued to sell to the public even after the FDA notified them that their product could not be sold without FDA approval. For these reasons, the district court's order of restitution was well within its discretion.

V.

Accordingly, we AFFIRM the district court's order of summary judgment in favor of the Government.

[Filed Sep. 13, 1999]

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 98-3310

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

UNIVERSAL MANAGEMENT SERVICES, INC., CORPORATION;
NATURAL CHOICE, INC. CORPORATION,
doing business as Natural Choice Products, Inc.;
PAUL M. MONEA, individual; PAUL A. MONEA,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Ohio at Cleveland.

Before: NORRIS and SUHRHEINRICH, Circuit Judges; RICE, District Judge.

JUDGMENT

THIS CAUSE was heard on the record from the district court and was argued by counsel.

IN CONSIDERATION WHEREOF, it is ORDERED that the judgment of the district court granting summary judgment in favor of plaintiff United States of America is AFFIRMED.

ENTERED by ORDER OF THE COURT

/s/ LEONARD GREEN
LEONARD GREEN
CLERK

APPENDIX B

[Filed Dec. 22 1997]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. 5:95CV 2768
Judge Solomon Oliver, Jr

UNITED STATES OF AMERICA,
Plaintiff

v.

UNIVERSAL MANAGEMENT SERVICES, INC., *et al.*,
Defendants

MEMORANDUM AND ORDER

Plaintiff, the United States of America ("Plaintiff"), brings this action against Defendants, Universal Management Services, Inc., Natural Choice, Inc., Paul M. Monea, and Paul A. Monea ("Defendants"). Currently pending before the court are summary judgment motions from both parties, including argument regarding whether disgorgement should be among the remedies should summary judgment be granted in favor of Plaintiff and Defendants' Motion For Clarification of an aspect of an earlier issued preliminary injunction. The court makes the following rulings: 1) Plaintiff's Motion For Summary Judgment (docket no. 65) is granted; 2) Defendants' Motion For Summary Judgment (docket no. 66) is denied; and 3) Defendants' Motion For Clarification (docket no. 88) is denied.

I.

The following facts are not in dispute. Defendants Universal Management Services, Inc., and Natural Choice, Inc. are Ohio corporations which are managed by Defendant Paul M. Monea and his son, Paul A. Monea. As part of their business, Defendants sell and distribute a product known as the Stimulator, and also a product that connects to the Stimulator known as the Xtender. The Stimulator is essentially a piezo-electric gas grill igniter, marketed as a pain relieving device. To produce the Stimulator, defendants purchase gas grill igniters and outfit them with finger grips. A user then places the tip of the Stimulator on his body, presses with his thumb on a plunger, and an electric current passes into that part of the body. Defendants' advertising literature states that, when applied to certain acupressure points, the Stimulator can relieve numerous kinds of pain (e.g., migraine headaches, swollen joints, allergies). The Xtender is an accessory that allows an individual to use the Stimulator to reach areas of the body otherwise difficult to reach (e.g., the spine).

II.

Federal Rule of Civil Procedure 56(c) governs summary judgment motions and provides:

> The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law . . .

Rule 56(e) specifies the materials properly submitted in connection with a motion for summary judgment:

> Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated there

> in. . . . The court may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories, or further affidavits. When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denial of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

However, the movant is not required to file affidavits or other similar materials negating a claim on which its opponent bears the burden of proof, so long as the movant relies upon the absence of the essential element in the pleadings, depositions, answers to interrogatories, and admissions on file. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

In reviewing summary judgment motions, the court must view the evidence in a light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970); *White v. Turfway Park Racing Ass'n, Inc.*, 909 F.2d 941, 943-44 (6th Cir. 1990). A fact is "material" only if its resolution will affect the outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases the court must decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." *Id.* at 252.

Summary judgment is appropriate whenever the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial. *Celotex*, 477 U.S. at 322. Moreover, "the trial court no longer has a duty to

search the entire record to establish that it is bereft of a genuine issue of material fact." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989) (citing *Frito-Lay, Inc. v. Willoughby*, 863 F.2d 1029, 1034 (D.C. Cir. 1988)). The non-moving party is under an affirmative duty to point out specific facts in the record as it has been established which create a genuine issue of material fact. *Fulson v. City of Columbus*, 801 F. Supp. 1, 4 (S.D. Ohio 1992). The non-movant must show more than a scintilla of evidence to overcome summary judgment; it is not enough for the non-moving party to show that there is some metaphysical doubt as to material facts. *Id.*

III.

As a preliminary note, given the overlap of issues in these motions and the preliminary injunction motion, the court, in ruling on these motions, will use some of the same factual analysis and legal discussion as in the preliminary injunction order. However, clearly a different evidentiary standard applies in the summary judgment context. In granting Plaintiff's motion for a preliminary injunction, the court concluded that

> Because defendants obtained from the FDA neither a PMA nor a finding of substantial equivalence, the Stimulator and Xtender are "adulterated" devices under the FDCA. This finding alone entitles the government to the injunctive relief it seeks. When the government seeks an injunction to protect the public health pursuant to statute, as here, it is not required to show irreparable harm, or inadequacy of a remedy at law. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. City of Painesville, Ohio*, 644 F.2d 1186, 1193 (6th Cir. 1981), *cert. denied*, 454 U.S. 894 (1981). Further, Congress has found that a violation of the FDCA, by itself, results in harm to the public, so there is no need to balance the equities. *Hecht Co. v. Bowles*, 321 U.S. 331 (1944); *United States v. Diapulse Corp. of America*, 457 F.2d 25, 28 (2nd Cir. 1972).

In reaching that conclusion, the court was acting as both the finder of facts and law in determining whether Defendants should be enjoined from certain activity pending a determination on the merits of the lawsuit. In the context of ruling on a summary judgment motion, however, the court plays a different role. Here, the court must determine "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." In making this determination, the court must view the evidence in a light most favorable to the non-moving party to determine whether a genuine issue of material fact exists.

A.

Plaintiff claims that Defendants' sales of the Stimulator and Xtender are violations of the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Specifically, the government claims that defendants have violated 21 U.S.C. § 331(a) and § 331(k), which prohibit misbranding or adulterating medical devices and introducing such devices into interstate commerce. Both Plaintiff and Defendants have now moved for summary judgment on these claims.

To show that Defendants have violated §§ 331(a) & (k), Plaintiff must prove: (1) the Defendants' products are "devices" within the meaning of the FDCA; (2) the devices are adulterated or misbranded; and (3) the devices move in interstate commerce. It is undisputed that Defendants' products move in interstate commerce. Consequently, Plaintiff must prove only that the products are adulterated or misbranded devices.

A device is "adulterated" under the FDCA if it is required to receive premarket approval ("PMA") from the Food & Drug Administration ("FDA"), but did not receive this PMA. 21 U.S.C. § 351(f)(1)(B); *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F.Supp. 990, 998 (W.D. Mich. 1985). Whether a device is required to receive a PMA from the FDA depends on a scheme set out in 21 U.S.C.

§ 360c. Under this scheme, all medical devices are categorized as Class I, Class II, or Class III devices. Class III devices are subject to stringent regulatory requirements, Class II devices are subjected to intermediate regulatory requirements, and Class I devices are subjected to minimal regulation. Further, under this scheme, medical devices are either "old devices," meaning they were on the market before 1976, or "new devices," meaning they were not on the market before 1976. All new devices are automatically Class III devices. 21 U.S.C. § 360c(f).

Class III devices cannot be marketed unless either: (1) the manufacturer has submitted to the FDA an application for PMA, and the application had been approved; or (2) the manufacturer submits a "premarket notification" arguing that its device should be reclassified as Class I or Class II because it is substantially equivalent to an existing Class I or Class II device, and the FDA finds that the devices are in fact substantially equivalent.

Defendants contend that their products are not violative of §§ 331(a) & (k) for three reasons. First, Defendants that their products are not devices within the meaning of the FDCA. The FDCA's definition of "device" is as follows:

> The term "device". . .means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intending to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being me-

> tabolized for the achievement of its primary intended purposes.

21 U.S.C. Sec. 321(h). Defendants assert that their products are not a devices because they (1) achieve their primary intended purpose through chemical action and (2) do not have any effect on the structure or function of the body. However, Defendants have pointed to nothing in the record that creates a genuine issue of fact as to whether their products achieve their primary intended purpose through chemical action. In fact, even Defendants' own witnesses, Dr. Roy Bugay and Dr. Robert Charm, both indicated that Defendants' products do *not* operate through chemical action. As such, Defendants' argument that their products are not devices because they achieve their primary intended purpose through chemical action is not well-taken.

Similarly, not only have Defendants failed to raise a genuine issue of material fact as to whether their products have any effect on the structure or function of the body, but they completely fail to point to anything in the record that even remotely suggests that their products do not have any effect on the structure or function of the body. In fact, Defendants own description of their products leads to only one reasonable conclusion, i.e., Defendants' products have an effect on the structure and/or function of the body. In Defendants' motion for summary judgment, Defendants describe the Stimulator as working as follows:" 'the [] electrical stimuli [from the device] . . . stimulate excitatory cells which release electrical potentials which set off a chain of . . . reactions that send messages to the brain creating a responsive reaction that organizes peptides to return the body to homeostasis."

It is disingenuous of Defendants to assert that this returning of "the body to homeostasis" is not an attempt to affect the function of the body. Additionally, Defendants assert that the Stimulator "has been found to provide relief for certain ailments," i.e. pain. Pain is a function of the body, and therefore intent to relieve pain is intent to affect that function. *United*

States v. Undetermined Quantities of Device, [1981-1982 Transfer Binder] Med. Dev. Rep. (CCH) Para. 15,055, at p. 14,377 (W.D. Mich. Nov. 22, 1982) ("[P]ain is a physical warning signal produced by the body to indicate that a problem within the body exists. As such, it is a function of the body."). Consequently, the court concludes as a matter of law that both the Stimulator and the Xtender are intended to affect the structure or function of the body, and therefore, are "devices" within the meaning of the FDCA.

Second, Defendants contend that even though the Stimulator did not receive a PMA, the Stimulator is not "adulterated" because it is similar to a device marketed prior to May 28, 1976, thereby obviating the need for PMA. However, the only "evidence" submitted in support of such assertion is Defendants' conclusory claim that "[t]estimony by Steve Michelson and his exhibits demonstrate the Stimulator is . . . identical to a preamendment device." Given that Defendants have not fulfilled their duty of pointing out specific facts in the record which create a genuine issue of material fact on this point, the court concludes that Defendants' assertion that the Stimulator is similar to a device marketed prior to May 28, 1976 does not create a genuine issue of material fact thereby precluding summary judgment.

Defendants also assert that the Stimulator is not subject to PMA because it is exempt from approval by current FDA statutes and regulations. This argument is based on the contention that the Stimulator is identical to another device, the "Accu-Magic," which is "listed"[1] with the FDA as a therapeutic

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[1] The device listing requirement, 21 U.S.C. Sec. 360(j), is simply a means by which the MDA keeps a current inventory of devices marketed in the United States. See, e.g., H.R. Rep. No.92-924, at 1 (1972) (discussing the purpose behind the Drug listing Act of 1972); H.R. Rep. No. 94-853 at 18 (1976) (adding listing requirement for devices). A submitter's charcterization of advice in its listing form in not relied upon for purpose of Classification.

massage device- a class of products exempt from the premarket clearance requirement of the Medical Device Amendments to the FDCA. Therefore, Defendants contend that the Stimulator should be treated the same as the "Accu-Magic" device and not be required to receive premarket clearance.

In its preliminary injunction order, the court concluded that Defendants' suggestion that their product is a "therapeutic massager" and thus exempt from the FDA regulatory scheme was "completely without merit." However, Defendants, in their supplementary memorandum in support of their motion for summary judgment, have submitted additional information that the court must evaluate to determine whether Defendants have raised a material issue of fact. Defendants have submitted attachments which indicate that the FDA has accepted registration of the device, the "Accu-Magic," which is identical to the Stimulator, as a Class I device, which are exempt from registration under the more rigid Class III standards, which require premarket approval. However, in its reply brief, Plaintiff has submitted a May 29, 1997 letter from Lilliam Gill of the FDA to the Accu-Magic company informing Accu-Magic that its product is not a therapeutic massager and that it is not exempt from premarket clearance. Given Defendants insistence that the Stimulator is "identical" to the "Accu-Magic" product, the Stimulator is subject to a similar fate.

Additionally, even if the court found Defendants' above-mentioned argument persuasive, given that the Stimulator is a Class III device, Defendants cannot legally market the Stimulator unless they have obtained from the FDA either a PMA or a finding of substantial equivalence. Defendants do not argue they obtained a PMA. However, as discussed above, Defendants do argue that the Stimulator should be reclassified as Class I or Class II because it is substantially equivalent to existing, lawfully marketed, Class I or Class II devices. Defendants' product can only be found substantially equivalent to existing legally marketed devices, however, if the FDA so finds in an order; the defendants cannot dub it so themselves. 21

U.S.C. § 360c(i); *Thor of Genesis*, 885 F. Supp. at 1028. There is no question that the FDA has not found (and defendants never applied to the FDA for a finding) that the challenged products are substantially equivalent to other lawfully marketed devices. Consequently, the court concludes as a matter of law that because the Stimulator and the Xtender are Class III devices and therefore subject to PMA, Defendants failure to receive such PMA renders their products "adulterated."

In sum, the court has found that the undisputed material facts indicate that both the Stimulator and the Xtender are "devices" within the meaning of the FDCA; (2) the devices are adulterated; and (3) the devices move in interstate commerce. Thus, the court hereby grants summary judgment in favor of Plaintiff. Consequently, Defendants motion for summary judgment is denied.

B.

In its initial Complaint in this case, in addition to an injunction, Plaintiff asked the court for "its cost and such other relief as the court deems just and proper, including but not limited to equitable disgorgement of profits gained by Defendants from the sale of adulterated and misbranded medical devices." After reading the parties' briefs and evaluating the relevant case law, the court concludes that although disgorgement is a remedy within the court's power to order in this case, such remedy is not the most appropriate in this matter.

While numerous district courts have ordered the equitable remedy of disgorgement in a variety of FTC cases, neither the parties nor the court could find an FDA case where disgorgement of profits was ordered. While the lack of previous use of the equitable remedy of disgorgement of profits in FDA cases is not necessarily fatal to Plaintiff's request for such a remedy, such nonutilization does cast some doubt on the appropriateness of disgorgement in this matter. While the court will not order disgorgement of profits in this case, the court does find

that restitution is both available and appropriate. Such remedy will ensure that the public interest is protected by providing each person who purchased Defendants' adulterated product the opportunity to receive his money back.

In *Federal Trade Commission v. Gem Merchandising Corporation*, 87 F.3d at 469, the Eleventh Circuit upheld the District Court's ability to order both injunctive and equitable relief and noted:

> In *Porter*, [*Porter v. Warner Holding Co.*, 328 U.S. 395, 66 S. Ct. 1086, 90 L.Ed. 1332 (1946)] the Supreme Court upheld the district court's authority to refund illegal rent overcharges pursuant to section 205(a) of the Emergency Price control Act of 1942, which expressly granted only the power to enjoin illegal practices. In so holding, the Court wrote that
>
> > [u]nless otherwise provided by statute, all the inherent equitable powers of the District court are available for the proper and complete exercise of that jurisdiction. And since the public interest is involved in a proceeding of this nature, those equitable powers assume an even broader and more flexible character than when only a private controversy is at stake. Power is thereby resident in the District court, in exercising this jurisdiction, "to do equity and to mold each decree to the necessities of the particular case." *Hecht Co. v. Bowles*, 321 U.S. 321, 329, 64 S. Ct. 587, 591, 88 L.Ed. 754 [(1994)] . . . .
>
> > Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied. *Porter*, 328 U.S. at 398, 66 S. Ct. at 1089 (citations omitted).

> As *Porter* makes clear, absent a clear command to the contrary, the district court's equitable powers are extensive. Among the equitable powers of a court is the power to grant restitution and disgorgement. *See, e.g., FTC v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1316 (8th Cir. 1991) (restitution); *Amy Travel Service*, 875 F.2d at 570 (restitution); SEC *v.* Blatt, 583 F.2d 1325, 1335 (5th Cir. 1978) (disgorgement).

In light of this above-analysis, the fact that the FDCA does not contain a clear command indicating that restitution is not a remedy within a district court's power, coupled with the Supreme Court's admonition that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health," *United States v. An Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969), the court is convinced that not only is ordering restitution within its power in this matter, but that such remedy is appropriate. Such a remedy will send a message to both Defendants and others engaged in similar behavior that if they violate the law, they will not be able to keep the proceeds from such illicit activity, but instead will have to refund all customers the purchase price of the adulterated goods.

Given that the court has considered the Complaint, both parties' summary judgment motions, the memorandum of law filed in support, and all related documents, and finds that Defendants have violated the law and, unless restrained by Order of the court, may continue to violate the FDCA, and summary judgment having been granted for the Plaintiff;

IT IS HEREBY ORDERED that:

The court has jurisdiction over the subject matter and over all parties to this action.

1. The Complaint for Injunctive and Equitable Relief states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395.

2. Defendants, Paul M. Monea, and Paul A. Monea, individuals, and Universal Management Services, Inc., and Natural Choice, Inc., doing business as Natural Choice Products, Inc., corporations, and each of their directors, officers, agents, servants, employees, successors, assigns, attorneys, and any persons in active concert or participation with any of them, shall permanently be enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done the importing, procuring, receiving, manufacturing, assembling, preparing, processing, packing, labeling, promoting, holding, distributing, shipping, or selling of any device as defined in 21 U.S.C. § 321(h), unless and until:

   a. All facilities in which Defendants manufacture, assemble, prepare, process, pack, or label devices are registered as required by 21 U.S.C. § 360; *and*

   b. All devices owned by Defendants, under their custody or control, or in any manner associated with Defendants are included in a list as required by 21 U.S.C. § 360(j), *and* with respect to each such device, one of the following has occurred:

      i. The Food and Drug Administration (FDA) has received a premarket notification as required by 21 U.S.C. § 360(k) for the device and has determined pursuant to 21 U.S.C. § 360c(I)(1)(A) that the device is substantially equivalent to a device for which premarket approval is not required; or

      ii. An FDA approved application for premarket approval, filed pursuant to 21 U.S.C. § 360e, for such device is in effect; or

iii. An FDA approved investigational device exemption, filed pursuant to 21 U.S.C. § 360j(g) and 21 C.F.R. Part 812, for such device is in effect, and the use and distribution of the device conforms to those requirements; and

c. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs III.A. and III.B. of this Order.

3. All devices, including each component, part, and accessory thereof, in the possession or control of Defendants or in any manner associated with Defendants as of the date of entry of this Order shall be destroyed within sixty (60) days of the date of entry of this Order, at Defendants' expense under FDA's supervision and in accordance with all federal and state laws and regulations, unless within sixty (60) days of the date of entry of this Order, Defendants have submitted in writing to FDA and FDA has approved in writing a plan to attempt to bring those devices into compliance with the Act (the "Reconditioning Plan"). If during any thirty (30) day period after approval of the Reconditioning Plan by FDA, in FDA's judgment, Defendants have made no good faith efforts to implement the Reconditioning Plan, all devices subject to this paragraph shall be destroyed immediately thereafter at Defendants' expense under FDA's supervision and in accordance with all federal and state laws and regulations. If Defendants do not destroy devices as required by this paragraph, FDA shall have the right to seize and destroy those devices without notice to Defendants and without Defendants' consent, and to require Defendants to pay all costs associated with that destruction.

4. Defendants may not attempt to bring any devices subject to Paragraph IV of this Order into compliance until they have received written authorization from FDA to do so. No articles that have been reconditioned pursuant to Paragraph

IV of this Order may be released or delivered for introduction into commerce unless and until FDA has authorized in writing such release or delivery. Before authorizing such release or delivery, FDA may require Defendants to provide written information, such as the names and addresses of all purchasers of the reconditioned articles, as the agency deems necessary to determine the acceptability to the agency of the release or delivery.

Within thirty (30) days of the date of entry of this Order, Defendants shall provide in writing to FDA: (1) the full names, addresses, and phone numbers of all entities and individuals who, at any time, have been involved in the importing, procuring, receiving, manufacturing, assembling, preparing, processing, packing, labeling, promoting, holding, distributing, shipping, or selling of any device in any manner associated with Defendants including but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof, and a detailed description of the involvement, including the time frame thereof, of each entity and individual; (2) the full names, addresses, and phone numbers of all entities and individuals who, at any time, have supplied or manufactured components, parts, or accessories for any device in any manner associated with Defendants including but not limited to the Stimulator and the Xtender, and a detailed description, including the name and address of the manufacturer thereof and the quantity thereof, of the components, parts, and accessories supplied or manufactured by each entity and individual; (3) the addresses of all locations where any device in any manner associated with Defendants including but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof, at any time, has been imported, procured, received, manufactured, assembled, prepared, processed, packed, labeled, promoted, held, distributed, shipped, or sold, and a detailed description of the importing, procuring, receiving, manufacturing, as-

sembling, preparing, processing, packing, labeling, promoting, holding, distributing, shipping, or selling that was done at each location and when it was done at each location; (4) the full names, addresses, and phone numbers of all entities and individuals who, at any time, have purchased fifty (50) or more of any device in any manner associated with Defendants including but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof, from Defendants or anyone acting on behalf of or associated with any of them; and (5) the full names, addresses, and phone numbers of all entities and individuals who have, or at any time have had, any rights to import, procure, receive, manufacture, assemble, prepare, process, pack, label, promote, hold, distribute, ship, sell, or otherwise transact business with respect to any device in any manner associated with Defendants including but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof, and a detailed description of the rights of each entity and individual.

5. Defendants and each of their directors, officers, agents, servants, employees, successors, assigns, attorneys, and any persons in active concert or participation with any of them, are permanently enjoined from directly or indirectly doing or causing to be done any of the following acts: (1) violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any article of device that is adulterated or misbranded; (2) violating 21 U.S.C. § 331(k) by causing the adulteration or misbranding of any article of device while the device is held for sale after shipment in interstate commerce of the device or one or more of its components; and (3) violating 21 U.S.C. § 331(p) by failing to register in accordance with 2 1 U.S.C. § 360, or by failing to provide listing information required by 21 U.S.C. § 360(j) or premarket notification information required by 21 U.S.C. § 360(k).

6. Defendants immediately shall institute, as FDA deems necessary, recalls of devices imported, procured, received, manufactured, assembled, prepared, processed, packed, labeled, promoted, held, distributed, shipped, or sold by Defendants or anyone acting on behalf of any of them.

7. If at any time following resumption of operations as authorized by Paragraph III of this Order, Defendants fail to comply with the Act or the requirements of this Order, FDA may notify Defendants in writing of Defendants' failure to comply and may require Defendants to halt immediately all importing, procuring, receiving, manufacturing, assembling, preparing, processing, packing, labeling, promoting, holding, distributing, shipping, or selling of devices. Upon receipt of such notice, Defendants shall immediately halt all such activity. A written notice by FDA pursuant to this paragraph shall remain in effect unless and until FDA rescinds or modifies that notice in writing.

8. FDA representatives are authorized, as is reasonably necessary to inspect Defendants' facilities and all equipment, finished and unfinished materials and product, containers, labeling, and other promotional material therein, to take photographs, videotapes, and sound recordings, and to examine and copy all records relating to the importing, procuring, receiving, manufacturing, assembling, preparing, processing, packing, labeling, promoting, holding, distributing, shipping, or selling of any of Defendants' products, of components, parts, or accessories of those products, of labeling for those products, or of promotional material for those products, to assure continuing compliance with the terms of this Order. Such inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. As a part of the inspections authorized under Paragraph X of this Order, upon written or oral request by FDA, Defendants shall provide to FDA access to their complete computer system, including all current and out-dated backup tapes and disks, for 3 full days (and longer if necessary) from 9:00 a.m. to 5:00 p.m. in order to create a backup of the entire system and perform any other functions determined by FDA to be necessary. During this period, Defendants shall make available all documentation related to the computer system, and shall make available, in person, both their system expert and an individual who has knowledge of all passwords, knowledge of how data is entered into the computer system, knowledge of how the computer software operates, knowledge of what specific data fields represent, and knowledge of how to create a backup of the system.

10. Defendants shall reimburse FDA for the costs of all FDA inspections, examinations, supervision of reconditioning, or other work done pursuant to any part of this Order at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Order, those rates are $53.73 per hour or fraction thereof per representative for inspection work; $64.43 per hour or fraction thereof per representative for analytical work; and 31 cents per mile for travel expenses. Defendants shall also reimburse FDA for the prevailing subsistence expenses for government employees. In the event that the standard rates generally applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

11. Within five (5) days of the date of entry of this Order, Defendants shall serve a copy of the Order, by personal service or certified mail (restricted delivery, return receipt requested), on each of their directors, officers, agents, servants, employees, successors, assigns, attorneys, and any persons in active concert or participation with any of them.

Within ten (10) days of the date of entry of this Order, Defendants shall provide FDA and Plaintiff's attorneys with a notarized affidavit of compliance, signed under penalty of perjury by each of the two individual Defendants and by Defendants' attorney, stating the fact and manner of compliance with this paragraph and listing the names and positions of all persons so notified, and the date each was notified, and attaching a copy of the executed certified mail return receipts, and a copy of any correspondence served or mailed with the Order. Within ten (10) days of receiving a written or oral request from FDA or Plaintiff's attorneys for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation.

12. In the event that, at any time after entry of this Order, any individual or entity becomes a director, officer, agent, servant, employee, successor, assign, or attorney of any Defendant, or becomes a person in active concert or participation with any of those persons or with any Defendant, Defendants shall: (1) within five (5) days serve a copy of the Order, by personal service or certified mail (restricted delivery, return receipt requested) on that person; and (2) within five (5) more days provide FDA and Plaintiff's attorneys with a notarized affidavit of compliance, signed under penalty of perjury by each of the two individual Defendants and by Defendants' attorney, stating the fact and manner of compliance with this paragraph and listing the names and positions of all persons so notified, and the date each was notified, and attaching a copy of the executed certified mail return receipts, and a copy of any correspondence served or mailed with the Order. Within ten (10) days of receiving a written or oral request from FDA or Plaintiff's attorneys for any information or documentation that FDA deems necessary to evaluate compliance with

this paragraph, Defendants shall provide such information or documentation.

13. Defendants shall notify FDA in writing at least ten (10) days before any reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Universal Management Services, Inc., Natural Choice, Inc., or Natural Choice Products, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance obligations arising out of this Order. Defendants shall: (1) within five (5) days of the emergence of a successor, assign, subsidiary, or other affiliated corporate entity, serve a copy of this Order by personal service or certified mail (restricted delivery, return receipt requested) on that new entity; and (2) within five (5) more days provide FDA and Plaintiff's attorneys with a notarized affidavit of compliance, signed under penalty of perjury by each of the two individual Defendants and by Defendants' attorney, stating the fact and manner of compliance with this paragraph and listing the names and positions of all persons so notified, and the date each was notified, and attaching a copy of the executed certified mail return receipts, and a copy of any correspondence served or mailed with the Order. Within ten (10) days of receiving a written or oral request from FDA or Plaintiff's attorneys for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation.

14. This Order shall apply to all of Defendants' successors or assigns, including any licensees or any other persons with rights to import, procure, receive, manufacture, assemble, prepare, process, pack, label, promote, hold, distribute, ship, sell, or otherwise transact business with respect to any device in any manner associated with Defendants in-

cluding but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof.

15. Any notices or other information this Order requires Defendants to give to FDA shall be given in writing via registered mail to the District Director, Cincinnati District Office, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

16. FDA's decisions under this Order shall be reviewed, if necessary, under the arbitrary and capricious standard of 5 U.S.C. § 706(2)(A).

17. Within forty-five (45) days of the date of entry of this Order, Defendants shall provide to Plaintiff's attorneys all records that in any way relate to the distribution of the Stimulator and the Xtender from May 4, 1995, to the date of entry of this Order, including but not limited to: all records relating to purchase or receipt of the Stimulator, the Xtender, or any components, parts, or accessories of either of them; all records relating to sale or shipment of the Stimulator, the Xtender, or any components, parts, or accessories of either of them; all accounting records for Defendants; all state and federal tax returns for Defendants for each tax year beginning in 1994 and ending in the year of entry of this Order; all records from all bank accounts that hold or at any time have held funds related to the Stimulator or the Xtender; and all records relating to income of Defendants related to the Stimulator or the Xtender, including but not limited to records of sales receipts, commissions, salaries, or licensing fees.

18. Within thirty (30) days of the date of entry of this Order, Defendants shall provide to Plaintiff's attorneys the names and addresses of all individuals and entities who have purchased one or more Stimulator or Xtender device(s) at any time from May 4, 1995, to the date of entry of this Order, and the amount of money spent by each individual and entity.

19. Within forty-five (45) days of the date of entry of this Order, Defendants shall submit to Plaintiff's attorneys a proposed notice to every individual and entity who has purchased one or more Stimulator or Xtender device(s) at any time from May 4, 1995, to the date of entry of this Order indicating that if they desire and indicate so in writing, they are entitled to a full refund of the purchase price of such device(s). If Plaintiff's attorneys find said proposed notice acceptable, Defendants shall, at their own expense, send such notices within thirty (30) days of Plaintiff's approval of the notices to every individual and entity who has purchased one or more Stimulator or Xtender device(s) at any time from May 4, 1995, to the date of entry of this Order. If the parties cannot agree on the nature or wording of the notice, such dispute should be promptly submitted to the court for resolution.

20. Within sixty (60) days of the date of entry of this Order, Defendants shall submit to Plaintiff's attorneys the full names, addresses, and phone numbers of all entities and individuals who, at any time, have purchased any device in any manner associated with Defendants including but not limited to the Stimulator, the Xtender, and each component, part, or accessory thereof, from Defendants or anyone acting on behalf of or associated with any of them.

21. Where necessary to implement the requirements of this Order or ensure compliance with this Order, attorneys for Plaintiff may, for a period of two (2) years following the date of entry of this Order, conduct further discovery on any issue related to this Order.

22. If any Defendant(s) violates this Order and is found in civil or criminal contempt thereof, such Defendant(s) shall pay a fine of $5,000 for each day for which any violation is established.

23. If any Defendant(s) violates this Order and is found in civil or criminal contempt thereof, such Defendant(s) shall, in

addition to other remedies, reimburse Plaintiff for its attorney fees, including overhead, and all other costs related to contempt proceedings, including investigatory and administrative costs.

24. This Court retains jurisdiction over this action and the parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may hereafter be necessary or appropriate.

C.

The only remaining issue is Defendants' Motion For Clarification. In its prior order, the court ordered that until several still unfulfilled conditions had been met:

> Defendants, as well as each and all of their directors, officers, agents, servants, employees, successors, assigns, attorneys, and any persons in active concert or participation with any of them, shall, during the pendency of this action, be enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done the importing, manufacturing, processing, packing, labeling, promoting, advertising, distributing, holding, or selling of any device, as defined in 21 U.S.C. § 321(h), unless and until:

> On November 7, 1997, Defendants filed a motion asking that "[b]ecause export is neither prohibited by the Court's Order nor the relevant statutes, Defendants respectfully request that the Court clarify its Order to reflect that Defendants may export their products."

The court's injunction prohibits the "distributing," "selling," "processing," "packing," and "labeling" of both the Stimulator and the Xtender. Clearly, all of these actions would be undertaken if Defendants' products were exported. Additionally, the court ordered that "[a]ll devices in the possession or control of defendants as of the date of entry of this order, except those devices that are brought into compliance with paragraph I of

this order, shall be destroyed . . . ." Obviously, a device that has been destroyed, by definition, cannot be exported. Consequently, if there was any doubt, the court's injunction includes prohibiting Defendants' products from being exported.

Defendants contend, however, that a statutory exemption in the Act permits the export of certain adulterated and misbranded medical devices. The exemption states, in relevant part:

> (1) A . . . device . . . intended for export shall not be deemed to be adulterated or misbranded under this chapter if it—
>
> (A) accords to the specifications of the foreign purchaser,
>
> (B) is not in conflict with the laws of the country to which it is intended for export,
>
> (C) is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) is not sold or offered for sale in domestic commerce . . . .
>
> (2) Paragraph (1) does not apply to any device—
>
> (A) which does not comply with an applicable requirement of section . . .360e of this title [pertaining to premarket approval requirements], . . .

unless, in addition to the requirements of paragraph (1), [FDA] has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.

21 U.S.C. Sec. 381(e).

Under 21 U.S.C. Sec. 381(e)(2)(A), the exemption "does not apply to any device" that fails to "comply with an applicable requirement of . . . [21 U.S.C. Sec.] 360e," relating to premarket approval of medical devices, unless the FDA issues the

statutorily-required determination permitting exportation. Because the court found that Defendants' devices did not comply with applicable premarket approval requirements and Defendants did not request an FDA determination that would allow the exportation of their devices, Defendants cannot qualify for the export exemption in 21 U.S.C. Sec. 381(e). Accordingly, Defendants' Motion For Clarification is denied.

IT IS SO ORDERED.

/s/ Solomon Oliver, Jr.
United States District Judge

[Filed Dec. 22, 1997]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Case No. 5:95CV 2768
Judge Solomon Oliver, Jr.

UNITED STATES OF AMERICA,
Plaintiff

v.

UNIVERSAL MANAGEMENT SERVICES, INC., *et al.*,
Defendants

JUDGMENT ENTRY

The court, having granted summary judgment in favor of Plaintiff, as well as permanent injunctive relief in its favor by a separate order on this same date, now enters judgment accordingly, in favor of Plaintiff and against Defendants.

IT IS SO ORDERED.

/s/ Solomon Oliver Jr.
United State District Judge